To Err Really is Human: Misunderstanding Medication Labels

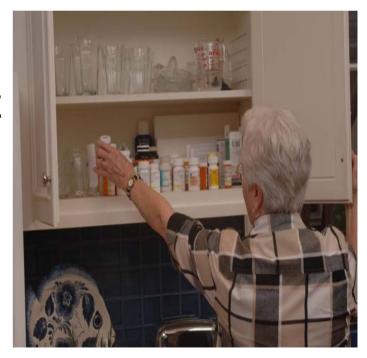


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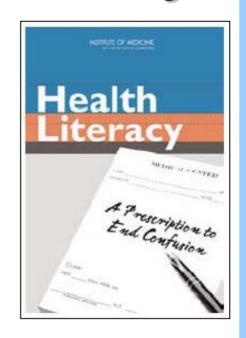
Overview

- What is health literacy?
- What is a medication label?
- What do we know about health literacy and medication labels?
- How can we improve OTC drug labels?



IOM Report on Health Literacy

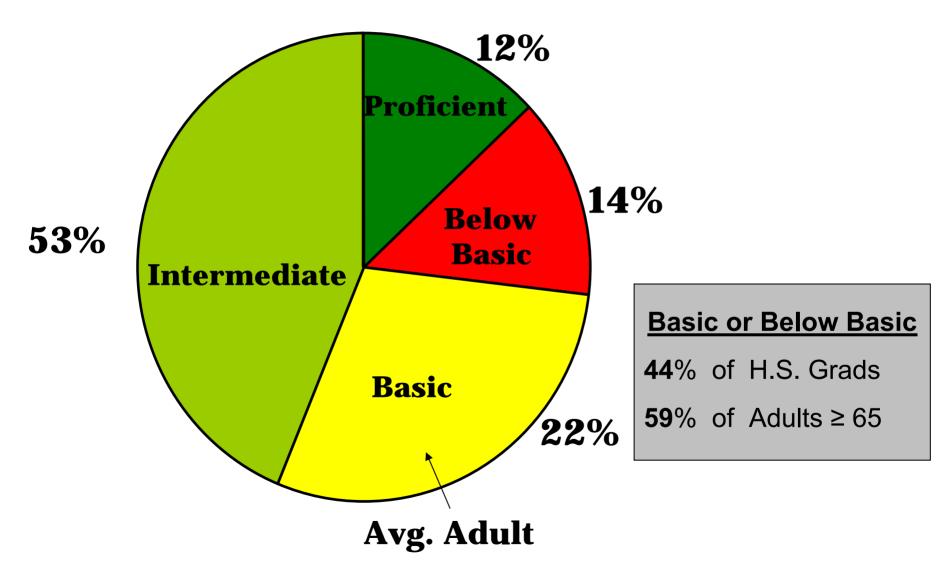
- 90 million adults have trouble understanding and acting on health information
- Complex text must be simplified and attention paid to culture and language



Healthy People 2010

 Improve health communication/health literacy

Health Literacy of America's Adults

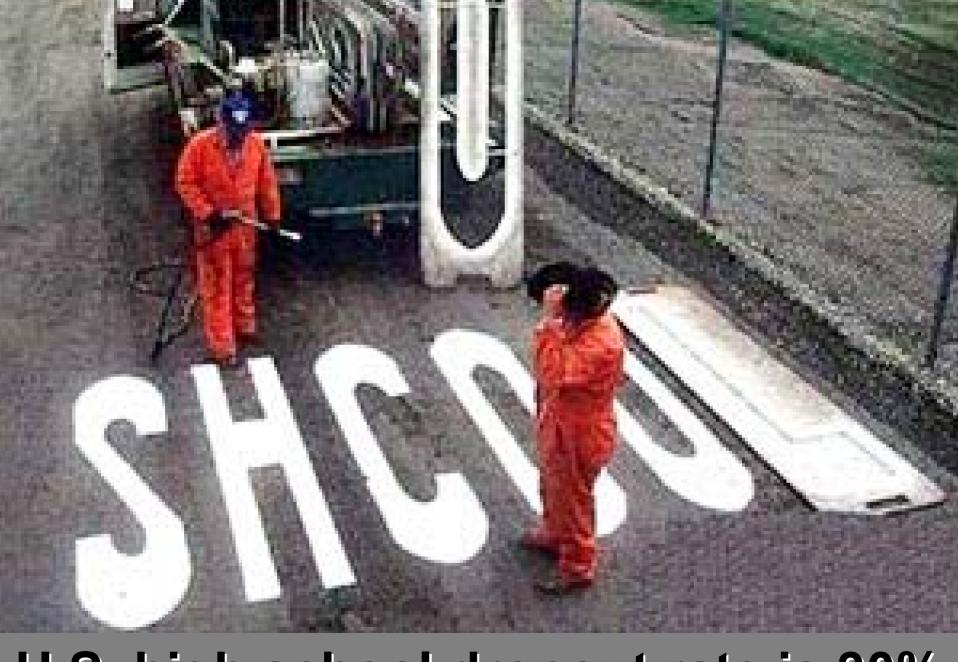


National Assessment of Adult Literacy (NAAL): National Center for Educational Statistics, U.S. Department of Education, 2003.

77 M Adults - Basic or Below Health Literacy

- •Cannot understand how to take Rx medicines based on common label instructions
- •Cannot identify 3 substances that interact with an OTC drug based on the label





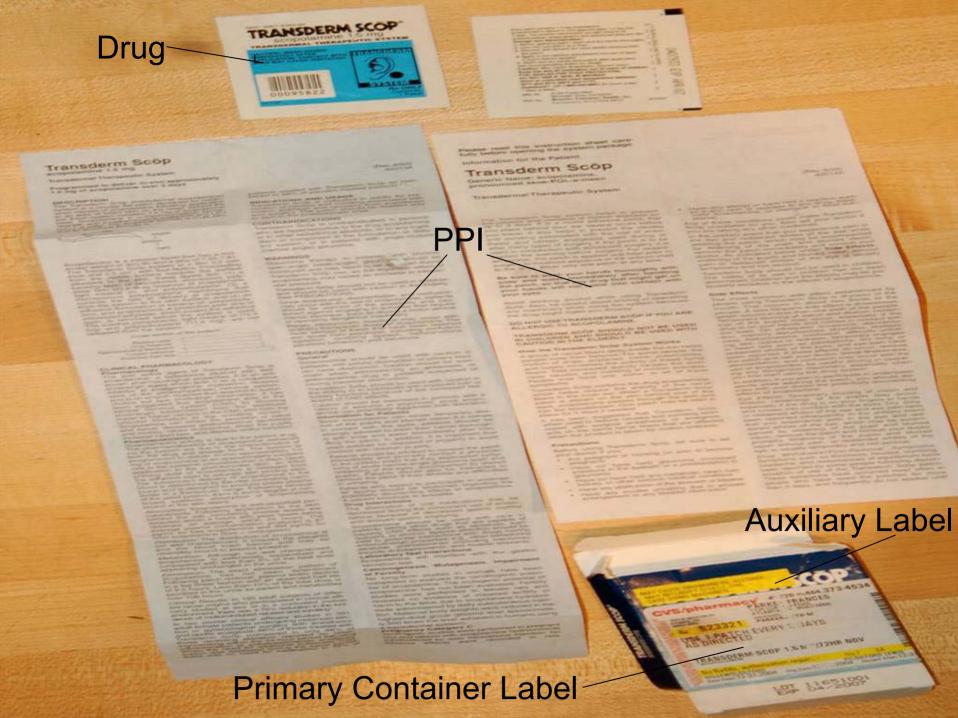
U.S. high school dropout rate is 30%

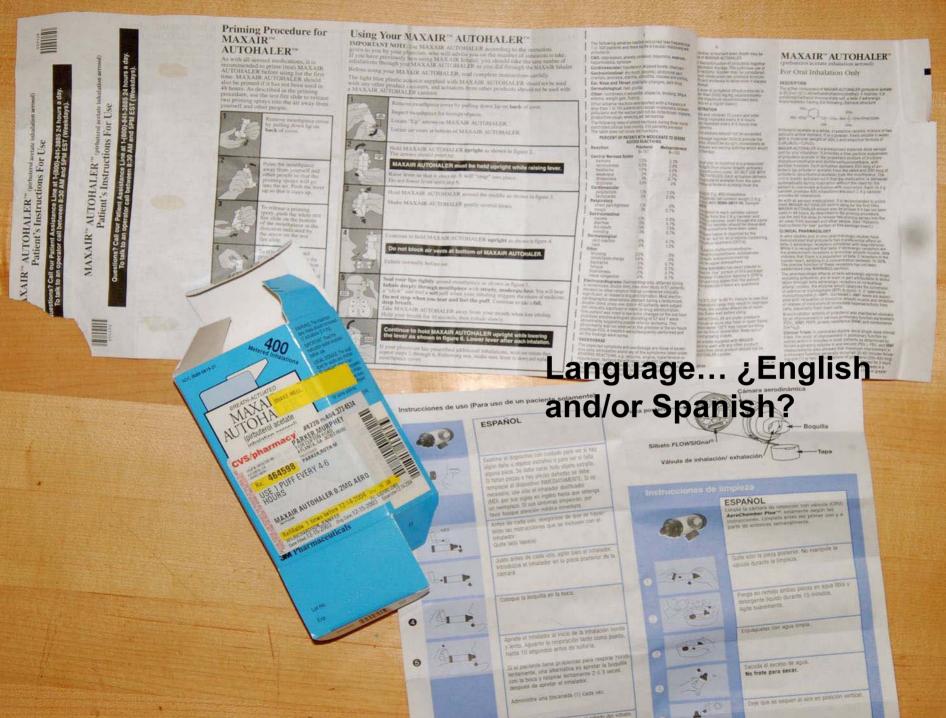
Video

You can't tell by looking

Medication Label A System of Information

- Primary container labels
 (state regulated, FDA requirements)
- Auxiliary Labels (Warning Labels)
 (industry-generated, not standardized)
- Consumer Medication Information (CMI) (industry-generated)
- Medication Guides-Prescription only for providers (28 developed by FDA)
- Patient Package Information (PPT)-for provider (written by manufacturer approved by FDA)





WAITING CVS/pharmacy S SHAROTHE S E TON MANY ANY CHESTRANS ABOUT FORM MEDICALISM, PLANS CONTACT TOUR PERSONALISM COMMETY, JOB, APA. COMMON ERANG NAMES! Leverple

#8728 ~404.373-4534 WWW.CVS.COM

LEVACUIN NOR MG TABLET MCN

Drug Storage Type Fact Moves

FDA and OTC Drug Labels

1966-Fair Packaging and Labeling Act
All consumer products in interstate commerce to
be honestly and informatively labeled

1999-Creation of Drug Facts Label for OTC's Required standard format for all OTC drug labels to give easy-to-find information

WHAT'S ON THE LABEL

All nonprescription, over-the-counter (OTC) medicine labels have detailed usage and warning information so consumers can properly choose and use the products.

Below is an example of what the new OTC medicine label looks like.

ACTIVE INGREDIENT

Therapeutic substance in product; amount of active ingredient per unit

USES

Symptoms or diseases the product will treat or prevent

WARNINGS

When not to use the product: conditions that may require advice from a doctor before taking the product; possible interactions or side effects; when to stop taking the product and when to contact a doctor; if you are pregnant or breastfeeding, seek guidance from a health care professional; keep product out of children's reach

PURPOSE

Product action or category (such as an antihistamine, antacid, or cough suppressant)

DIRECTIONS

Specific age categories, how much to take, how to take, and how often and how long to take

OTHER INFORMATION

How to store the product properly and required information about certain ingredients (such as the amount of calcium, potassium, or sodium the product contains)

INACTIVE INGREDIENTS

Uses emporally release these symptoms due to his fever or other upper respiratory elegation. His meeting a function one will be the wittern over the state of the

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Other information a scene sole; Call-17 p

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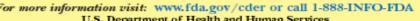
Prug Facts Active ingredient (in each teblet

> Substances such as colors or flavors

The Drug Facts labeling requirements do not apply to dietary supplements, which are regulated as food products, and are labeled with a Supplement Facts panel.

take 1 nattet energy 4 to 6 hours; not note than 6 inthint at hours; not note than 3 inthints in 24 hours; not note than 3 inthints in 24 hours;





Purpose

U.S. Department of Health and Human Services Food and Drug Administration



OTC Drug Facts

Do not use if the individual blister unit is open or tern. Read Package lesert before use

Drug Facts

Active ingredient (in each tablet) Famolides 20 mg

Uses -referves hearthurn associated with acid indigestion and

· acevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverage

Allergy alert Do cot use if you are abecome to famultiding or other acid reducers

Do not use

- · if you have trouble or pain ownlowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your dector.
- of you have kidney disease, except under the advice and supervision of a doctor
- with other acid reducers

Ask a doctor before use if you have

- + had heartburn over I months. This may be a sign of a more senous condition.
- · hearthum with lightheadedness, sweating, or dizziness chest pain or shoulder pain with shortness of breath;
- sweating, pain apreading to arms, neck or shoulders. or lightheadedness
- fraquent chest pain
- frequent wheezing, particularly with hearthurn unexplained weight loss
- nauses of vomiting

Drug Facts (continued)

Stop use and ask a doctor if

- · your hearthurn continues or worsens you need to take this product for more than 14 days
- If prognant or breast-feeding, ask a health professional
- Keep out of reach of children, in case of overdose, get medical help or contact a Poison Control Center

- adults and children 12 years and over
- · to refere syngtons, explow I tablet with a glass of water Do not chew.
- to prevent symptoms, swallow I tablet with a glass of water at any time from 10 to 50 minutes before eating food or drinking beverages that cause heartburn
- do not use more than 2 tablets in 24 hours
- children under 12 years; ask a doctor

Other information

- read the directions and warnings before use · keen the carton and package insert.
- They cortain important information. Fig. 28.70. The rote.
- protect from moisture

Inactive ingredients

camaida wax, hydrosytropyl cellulose, hydronellose, magnesium stearate, microcrystalline celiciose regulationsed starch, talc, thanks double

Questions or comments?

-506-755-4008 (English) or 1-508-405-4746 (Spanish)

Drug Facts

Active ingredient (in each tablet)

Panishdine 75 mg (as ramitidine hydrochloride (USP, 64 mg).

Uses

■ relieves hearthurn associated with acid indigestion and sour showaith was series his recent his recent associated with acid indivestion and soor comach brevent on by control toods and twistones.

Afterpy alert: Do not one if you are alterpic to randone or other and reduces

- Do not use: # if you have brouble swallowing # with other and restrict
- Stop use and ask a doctor if a stomuch pain continues
 - you need to take this product for more from 14 (p.v.

Purpus

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach at children. In case of overdose, get medical halo or contact a Posino Govern Center

Directions

- adults and children 12 years and over:
- to relieve symptoms, swallow 1 tablet with a place of water
- to prevent symptoms, invalid vi 1 tablet with a glass of water 30 to 60 minutes before curing load or drinking beverages that cause heartburn.
- can be used up to twice daily (up to 2 tablets in 24 hours)
- children under 12 years, ask a doctor

Other information

- ithis product is sodium and sugar free
- do not use if the carton or individual blister unit is open or form avoid excessive heat or humidity
- store at 20" 25" C (68" 77" F). (See USP Controlled Room Temperature)

Inactive ingredients castor oil, colloidal silicon dioxide, crossarmeliose sodium, hypromeliose, magnesium stearate, microcrystalline cellulose, red iron oxide, talc, titanium dioxide. May contain edible ink.

Read the directions, consumer information leaflet and warnings before use. Keep the carron. It contains important information.

If you have any questions of a medical nature, please contact your Pharmacist, Doctor or Health Care Provider.

Drug Facts Read the directions and warnings before taking this product. KEEP THE PRODUCT INFORMATION SHEET, IT CONTAINS INFORTANT INFORMATION.

Active ingredient (in each tablet) Ometane 200 mg.

Purpose Acid moucer

Uses - relieves hearthurn associated with acid indigestion and sour stomach prevents hearthum associated with acid indigestion and sour storach. brought on by eating or drinking certain food and beverages

Allergy alert: Do not use if you are allergo to cimetidine or other and reducers.

Do not use

- if you have trouble or pain swallowing load, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor
- · with other acid reducers

Ask a doctor before use if you have

- · frequent chest pain · frequent wheezing, particularly with hearthum
- unexplained weight loss.
 nauses or vorsting.
 stomach pain.
- had hearfourn over 3 months. This may be a sign of a more serious condition.
- hearthurn with lightheadedness, sweating or dizziness
- · chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness.

Ask a doctor or pharmacist before use if you are taking

- theophyline (oral astima medicine) wartarn (blood thinning medicine)
- přenyton (sezure medone) if you are not sure you are being one of these medioners, talk to your doctor or pharmacist.

Stop use and ask a doctor if

- · your hearthurn continues or worsens · stomach pain continues
- · you need to take this product for more than 14 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poson Control Center right away.

Directions

- · adults and children 12 years and over:
- to reserve symptoms, swallow 1 tablet with a glass of water
- to prevent symptoms, swallow 1 tablet with a plass of water right before or any time up to 30 minutes before eating lood or drinking beverages that cause hearthum
- + do not take more than 2 tablets in 24 hours children under 12 years, ask a dodor

Other information - store # 15-30*C (55-86)

Inactive ingredients calulose, com starch ypromelicie, magnesium steamite, polyethylene acci, pointortate 80, pointore, sodum laury sufficie, sodium starch glycotate, stanium dioxide

Questions or comments? all tol-free 1-800-462-4394 (English Spanish) seekdays



PPI for OTCs

FDA requires insert for limited number of OTC drugs

- Vaginal sponges
- Vaginal anti-fungals
- H2 blockers
- Nicotine replacements





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How to use MAXIMUM STRENGTH PEPCID! AC

PERSONAL INVESTOR OF

Type the Managing Processors

RELIEVE SYMPTOMS.

TO PREVENT EVMPTONES

CVS Compare to the active ingredient in Zantac 75 RANITIDINE TABLETS USP, 75 mg/ACID REDUCER PREVENTS & RELIEVES **HEARTBURN Associated** with Acid Indigestion & Sour Stomach 10 Tablets

Ractions 75 mg What see

Resident

Tablets?

prevent?

What symptoms de Randidina Toblets heat and

How should I take Randigine Tablets?

New de Ranitidire Tablets word?

Additional tips for managing hearthurn.

What you should know about Ranitidine Tablets 75 mg Acid Reducer

Phone must all or the assessment before being franching Spring (Song) Save trop burse for suburn heterocons.

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Specific Green 75 mg release and present healthurn antecurse with any independent and your stomach.

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Ramons Spots 75 mg means the posturior of storage and. The model makes Ramons Sales. 25 mg offerent from process, which contrative the sciclarises in your promate. Artscots do not reduce THE STORY COLUMN OF STATE

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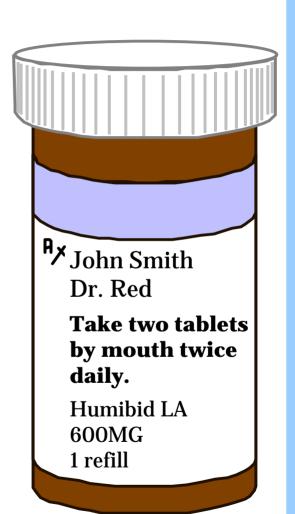






Hidden Problems with Medication Labels

- More than 10,000 Rx and 300,000 OTC in U.S. market
- Over 1/3 of U.S. adults cannot understand common dosing instructions on a pill bottle
- Poor understanding is a source of medication error and an issue of safety
- Simple label instructions are not always clear or understood



Video

Understanding medication labels: An issue of safety



One capsule twice daily

One tablet by mouth twice a day for 3 days

One tablet two times a day

One tablet by mouth twice a day

Tomar
1tab XLA
boca
vezdia X7
dias luego
do XLA
boca X7
dias

Take one by mouth 3? Times a day

Take as directed

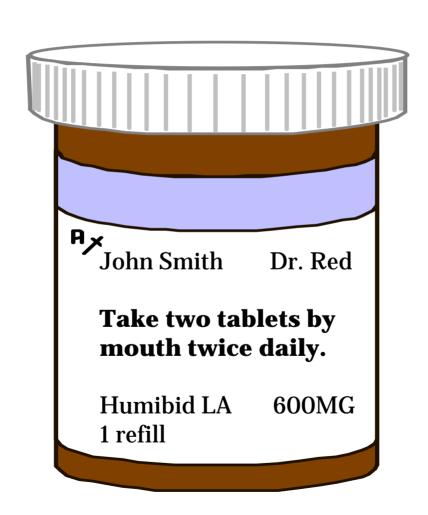
"How would you take this medicine?"

395 primary care patients in 3 states

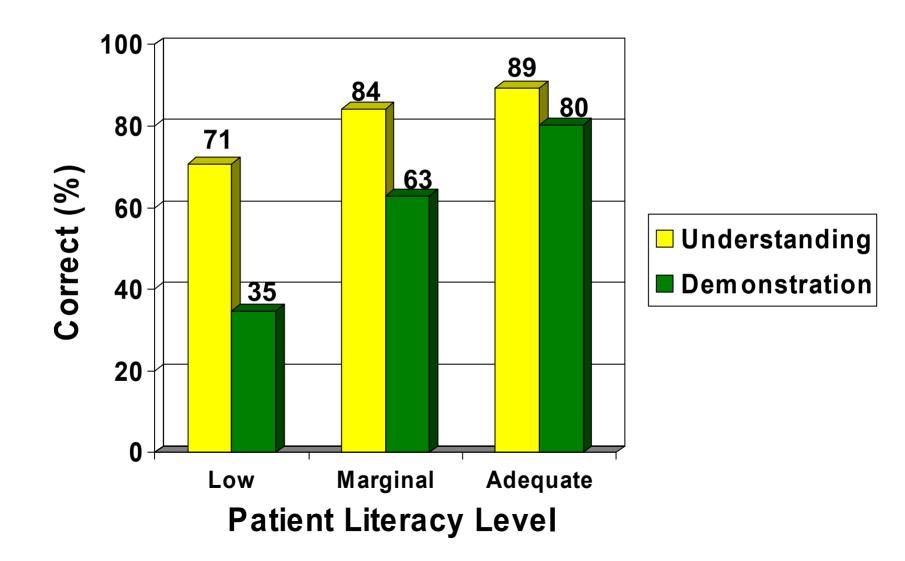


- 46% did not understand instructions ≥ 1 labels
- 38% with adequate literacy missed at least 1 label

"Show Me How Many Pills You Would Take in 1 Day"



Rates of Correct Understanding vs. Demonstration "Take Two Tablets by Mouth Twice Daily"



"What does this warning label mean?"



- 9 pharmacists and 5 physicians choose 8 commonly used warning labels
- 253 public health primary care patients were shown bottles one at a time

Simple familiar wording understood by most patients



84%

(1st gd.)

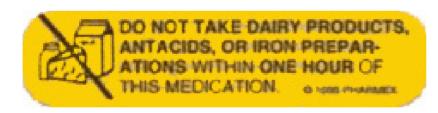
More complex message limited comprehension



59%

 $(10^{th}-12^{th} gd.)$

Unfamiliar multi-step instructions rarely understood



8%

(12th-13th gd. level)

Comprehension Increased with Patient Literacy Level

* p<.0001, † p<.05

	<u><6</u>	<u>7-8</u>	<u>>9</u>
TAKE WITH PROPERTY OF THE PROP	79%	86%	88%†
DO NOT CHEW OR CRUSH, SWALLOW WHOLE.	35%	66%	78% *
FOR EXTERNAL USE ONLY	8%	64%	82% *
REFRIGERATE-SHAKE WELL DISCARD AFTER	8%	18%	23% *
DO NOT TAKE DAIRY PRODUCTS, ANTACIDS, OR IRON PREPAR- ATIONS WITHIN ONE HOUR OF THIS MEDICATION. O 1988 99-AMMEX	0%	6 %	15% *

In multivarient analysis only literacy and age predicted comprehension.

Patients with low literacy (< 6th gd.) 3X more likely to incorrectly interpret warning labels.

What does this picture mean?



- "Someone swallowed a nickel"
- "Indigestion"
- "Bladder"
- "Looks like a ghost- Casper"

Does adding the words help?



- "Chew pill and crush before swallowing"
- "Chew it up so it will dissolve, don't swallow whole or you might choke"
- "Just for your stomach"

What does this picture mean?



- "Somebody is dizzy"
- "Don't touch this stuff"
- "Take anywhere"
- "Chills or shaking"
- "Someone is having an experience with God"

Does adding the words help?



- "Use extreme caution in how you take it"
- "Medicine will make you feel dizzy"
- "Take only if you need it"

Labels-short and simple, but not clear to many



Many need more specific, concrete information.

- "What time do I take them?"
- "Do I take every 4 or 6 hours?"
- "Do I take them with food?"
- "What if I can't afford a whole bottle?"

Conclusions

- Health literacy=skills + task complexity
 - -U.S. skill level not improving
 - "ordinary" adult lacks adequate skills
 - -task complexity (labels) need improvement

Research findings:

- -simple does not equal clear
- -current warnings confusing
- -limited evidence of "best practices" for labels

How to Improve OTC Labels?

- Find the best way to say it (Clarification)
- Always say it the same way (Standardization)
- Don't say more that you need to (Evidence)
- Make up your mind about language (Spanish?)
- Warn with an icon
- PPI's Information for advertising?